PTO/SB/08a (05-07)
Approved for use through 11/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Application Number		10568051	
	Filing Date		2006-02-10	
	First Named Inventor Mille		er	
	Art Unit		3743	
	Examiner Name (not y		yet assigned)	
	Attorney Docket Numb	er	PR60436USw	

					U.S.I	PATENTS	Remove		
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue D	)ate	Name of Pate of cited Docu	entee or Applicant ment	Releva	Columns,Lines where nt Passages or Relevant s Appear
	1	5182097		1993-01	-26	BYRON et al.			
	2	5861473		1999-01	-19	DECROSTA et	al.		
	3	6068789		2000-05	i-30	BARNES et al.			
	4	6241828		2001-06-05		BARNES et al.			
If you wis	h to ac	dd additional U.S. Pater	nt citatio	n inform	ation pl	ease click the	Add button.	<u>I</u>	Add
	U.S.PATENT APPLICATION PUBLICATIONS Remove								
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publica Date	tion	of cited Document		Releva	Columns,Lines where nt Passages or Relevant s Appear
	1	20050092679	A1	2005-05	i-05	WARBY			
If you wish to add additional U.S. Published Application citation information please click the Add button. Add									
FOREIGN PATENT DOCUMENTS Remove									
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>		Kind Code <sup>4</sup>	Publication Date	Name of Patented Applicant of cited Document	e or V	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

( Not for submission under 37 CFR 1.99)

Application Number		10568051		
Filing Date		2006-02-10		
First Named Inventor	Miller	Miller		
Art Unit		3743		
Examiner Name	(not yet assigned)			
Attorney Docket Number		PR60436USw		

	1	0134847	EP	A1	1985-03-27	Trutek Research Inc.				
	2	9312161	WO	A1	1993-06-24	Schering Corporation				
	3	02072448	WO	A1	2002-09-19	Chiesi Farmaceutici s.p.a.				
	4	03049786	WO	A2	2003-06-19	Glaxo Group Limited				
If you wish to add additional Foreign Patent Document citation information please click the Add button Add										
			NON-PATE	NT LITE	RATURE DO	CUMENTS	Remove			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.								
	1	ITFG/IPAC-RS COLLABORATION - CMC LEACHABLES AND EXTRACTABLES TECHNICAL TEAM; "Leachables and Extractables Testing: Points to Consider"; A Response to the FDA draft Guidances for Industry; March 27, 2001; pp. 1-36; <a href="https://www.fda.gov/ohrms/dockets/ac/00/reports/3657_rpt1.pdf">www.fda.gov/ohrms/dockets/ac/00/reports/3657_rpt1.pdf</a>								
	2	JOSEPH H. GROEGER & LESLIE M. COMPTON; "Identifying and Preventing Contamination from Pharmaceutical Packaging"; Medical Plastics and Biomaterials Magazine; May 1997; <a href="https://www.devicelink.com/mpb/archive/97/05/005.html">www.devicelink.com/mpb/archive/97/05/005.html</a>								
	3	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES - FOOD AND DRUG ADMINISTRATION - CDER; "Draft Guidance for Industry - Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products"; Chemistry, Manufacturing, and Controls Documentation; October 1998; pp. 1-62; <a href="https://www.fda.gov/Cder/guidance/2180dft.pdf">www.fda.gov/Cder/guidance/2180dft.pdf</a> >								
If you wish to add additional non-patent literature document citation information please click the Add button Add										
EXAMINER SIGNATURE										
Examiner Signature Date Considered										
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.										